

U.S. Patent Appln. No. 09/978,345  
Response to Office Action Mailed February 26, 2003

Docket No. 9500-1

### REMARKS

The amendments and remarks are in response to the Office Action dated February 26, 2003. At the time of the Office Action, claims 1-32 were pending in this application. This amendment is filed with a Request for a Two (2) Month Retroactive Extension of Time and authorization is given to charge the required fees to Deposit Account No. 50-0951.

In the Office Action, the specification and claims 1, 2-5, 9, 17, 19, and 22 were objected to because of minor informalities. Claim 6 was rejected under 35 U.S.C. §112 ¶(1) and claims 1-32 were rejected under 35 U.S.C. §112 ¶(2). Additionally, claims 18-21, 23-27 and 31 were rejected under 35 U.S.C. §101 and claims 1, 2, 6-8, 12-14, 17-19, 21-23, 28 and 29 were rejected under 35 U.S.C. §103(a). Claims 3-5, 9-11, 15, 16, 19, 24-27 and 30-32 were indicated to be allowable if rewritten to overcome the rejections under 35 U.S.C. §112 and to include all of the limitations of the base claim and any intervening claims. The rejections are set out in more detail below.

#### I. Objections of Minor Informalities

The specification and claims 1, 2-5, 9, 17, 19, and 22 were objected to because of minor informalities. Appropriate amendments have been made and withdrawal of all of these objections is respectfully requested.

#### II. Rejection Under 35 U.S.C. §112 ¶(1)

Claim 6 was rejected under 35 U.S.C. §112 ¶(1). In support of this rejection, the Office Action alleged that the specification lacks adequate description of detecting the change of the pulse signal of the radial artery by measuring a variation of the external pressure of the radial artery caused by the pulsation of the radial artery of the wrist.

In contrast to the Office Action's assertions, an enabling description of the subject matter recited in claim 6 was presented as originally filed. In particular, an enabling description of the subject matter of claim 6 was presented in the section of the detailed description discussing the Sixth Embodiment on page 19. Withdrawal of this rejection is respectfully requested.

#### III. Rejections Under 35 U.S.C. §112 ¶(2)

Claims 1-32 were rejected under 35 U.S.C. §112 ¶(2) as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Appropriate amendments have been made and withdrawal of all the §112 ¶(2) rejections is respectfully requested.

U.S. Patent Appln. No. 09/978,345  
Response to Office Action Mailed February 26, 2003

Docket No. 9500-1

**IV. Rejections Under 35 U.S.C. §101**

Claims 18-21, 23-27, and 31 were rejected under 35 U.S.C. §101 because the claimed invention is allegedly directed to non-statutory subject matter. Appropriate amendments have been made and withdrawal of all of the §101 rejections is respectfully requested.

**V. Review of Claims**

Prior to addressing the rejections under §103(a), a brief review of a few claims of the present application is appropriate. Claim 1 is directed to a non-invasive blood pressure measurement method which requires keeping the wrist at a posture so as to lower the tendons to a position near the radial artery and cause the radial artery to be close to the radius. In addition to other features recited in claim 2, this claim limits the step of keeping the wrist at a posture by reciting that an angle between approximately 100 and 170 degrees is formed between the dorsal side of the wrist and the dorsal side of the hand. Further, claim 17 is directed to a non-invasive blood pressure measurement apparatus based on the method claim 1, which comprises a wrist holding device for keeping the wrist at a posture to lower the tendons to a position near the radial artery and causing the radial artery to be close to the radius.

**VI. Rejections Under 35 U.S.C. §103(a)**

The Office Action rejected claims 1, 2, 6-8, 17, 21, and 23 under 35 U.S.C. §103(a) as being unpatentable over WO 97/12542 to Hon ("Hon '542") in view of U.S. Patent No. 5,840,037 to Tochikubo et al., ("Tochikubo"). Claims 1, 2, 6, 12, 14, 17, 21, 22, and 28 were also rejected under 35 U.S.C. §103(a) as being unpatentable over Hon in view of U.S. Patent No. 5,243,990 to Aung et al., ("Aung"). Additionally, the Office Action rejected claims 1, 2, 6, 7, 13, 14, 17, 18, 21, 23, and 29 under 35 U.S.C. §103(a) as being unpatentable over Hon '542 in view of U.S. Patent No. 4,869,261 to Penaz ("Penaz"). Further, claim 18 was rejected under 35 U.S.C. §103(a) as being unpatentable over to Hon '542 in view of Tochikubo and in further view of United States Patent No. 4,993,422 to Hon et al. ("Hon '422").

In contrast to the Office Action's assertions, Hon'542, Tochikubo, Aung and Penaz, do not require keeping a wrist of a patient at a posture which can lower a position of at least one tendon of the wrist near a radial artery to be measured as required by the method claim 1 and provided by the structure in claim 17. Additionally, the arm board 30 for holding wrist

U.S. Patent Appln. No. 09/978,345  
Response to Office Action Mailed February 26, 2003

Docket No. 9500-1

disclosed in Hon '542 can have any angle, or no angle at all, and thus does not teach or suggest keeping a patient's wrist at a posture which can lower a position of at least one tendon of the wrist near a radial artery to be measured and cause the radial artery to be close to a radius of the wrist. The function of the apparatus disclosed in Hon '542 is to stabilize the wrist, so as to eliminate interference of blood pressure monitoring caused by arm movement and to keep the patient in a comfortable posture. (Hon '542, page 9, lines 16-31 and page 10, lines 1-2). Therefore, there is an essential difference between this technical feature of Hon '542 and that of claims 1, 2 and 17 of the present invention.

Additionally, the apparatus of Hon '542 and the method of Tochikubo are based on the auscultatory method and the oscillometric method respectively. The current auscultatory, oscillometric and vascular unloading method do not require to keeping a particular posture of the limb to be measured, and do not even require stabilizing the limb to eliminate the interference of blood pressure monitoring caused by excessive limb movement. These methods do not teach or suggest such a limitation as these methods commonly use an inflatable cuff which wraps around a limb to compress an underlying artery and a pulse transducer, or an auscultatory sensor, for detecting the pulse signal of the artery. The precision of these blood pressure measurement methods are independent of the posture of limb to be measured, as long as the compressing area of their cuff is sufficient to accurately transmit the cuff pressure to the artery through the soft tissues in the limb and the detecting range of the pulse transducer, or auscultatory sensor, is sufficient to detect the relative change of the pulse signal of the artery.

Nevertheless, most of current wrist blood pressure meters are inaccurate and inconsistent. Our recent research also discovered that "it is actually very difficult to measure the blood pressure accurately on the wrist. ...., the measured blood pressure will vary greatly when the wrist turns with the long axis of the forearm as the axis of rotation, or when the hand bends towards the palm side or the back side of the hand." (Present Application, page 4, lines 22-25). Thus, prior methods and apparatuses that involve a cuff where compressing an area of the cuff is sufficient to accurately transmit the cuff pressure to the artery through the soft tissues in a limb are limited to blood pressure measurements at particular limbs, such as an upper arm and/or finger which possess simple anatomical structures. When such a method and/or apparatus is used to measure the blood pressure at a wrist, which has a complicated anatomical structure with non-homogeneous soft

U.S. Patent Appin. No. 09/978,345  
Response to Office Action Mailed February 26, 2003

Docket No. 9500-1

tissues, the accuracy and precision of a blood pressure measurement is dependent on not only the compressing area of the cuff, but also the angle of the wrist.

In order to explore the relationship between the precision of wrist blood pressure measurement and the angle of the wrist, we investigated the change of displacement, strain and stress distribution of different tissues in a wrist along with the change of turning angle and bending angle of the wrist compressed by the cuff. The research indicated that some tissues with higher rigidity, such as the tendons positioned on the both sides of the radial artery, can affect the pressure transmission in the wrist. Keeping the wrist at a specified posture can lower the position of the tendons near to the radial artery and cause the radial artery to be close to the radius, so that the cuff pressure can be transmitted accurately to the radial artery.

In stark contrast to Hon '542 discussing stabilizing the wrist to eliminate some noise interference of the blood pressure monitoring caused by arm movement and providing comfort to the patient, the present claims are directed to changing the pressure transmission in the wrist, so as to improve the precision of blood pressure measurement at wrist. Additionally, the blood pressure determination method or apparatus of Tochikubo, Aung and Penaz do not teach or suggest the features recited in claims 1, 2 and 17. Thus, Tochikubo, Aung, Penaz and Hon '542 cannot be combined to teach or suggest the features recited in claims 1, 2 and 17.

U.S. Patent Appln. No. 09/978,345  
Response to Office Action Mailed February 26, 2003

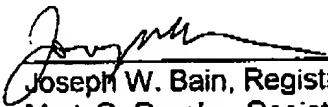
Docket No. 9500-1

VII. Conclusion

Applicant has made every effort to present claims which distinguish over the cited references, and it is believed that all claims are in condition for allowance. Therefore, Applicant invites the Examiner to call the undersigned if it is believed that a telephonic interview would expedite the prosecution of the application to an allowance. In view of the foregoing remarks, Applicant respectfully requests reconsideration and prompt allowance of the pending claims.

Respectfully submitted,

Date: 7/28/03

  
Joseph W. Bain, Registration No. 34,290  
Mark D. Passler, Registration No. 40,764  
AKERMAN SENTERFITT  
P.O. Box 3188  
West Palm Beach, FL 33402-3188  
Tel: (561) 653-5000

Docket No. 9500-1